

## REMARKS

1. This paper is responsive to the final Office Action mailed on November 25, 2008. Please charge Deposit Account No. 02-1818 for any fees deemed owed. In the Office Action, Claims 1, 7, 13, 24 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 2, and 5-12 are rejected under § 103(a) as unpatentable in view of U.S. Pat. No. 6,254,567 to Dennis Treu et al. ("Treu") in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). Claims 13, 14, 16-20, 22 and 23 are also rejected under 35 U.S.C. § 103(a) as unpatentable in view of Treu in view of Roberts. Claims 24-30 are also rejected under 35 U.S.C. § 103 (a) as being unpatentable in view of Treu and Roberts, as are Claims 3, 4, 15 and 21.

2. Claims 1, 13 and 24 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action states the phrase "consisting of" constitutes new matter in each of these claims and that the Examiner cannot find support in the specification and drawings for the claimed fluid circuit. Applicants point out that the application as filed also includes Figs. 3A and 3B, their description in paragraphs [0080] to [0082], and in paragraphs [0088] to [0091], as well as the claims themselves. A satisfactory description of an invention may be found in the claims or any other portion of the originally filed specification. M.P.E.P. 2163 I.

Claim 1 as filed, for example, recites a system with five claim elements: a catheter, a fluid circuit, a supply of dialysate coupled to the fluid circuit, a cyclor, and a discharge fluid path. Claim 10 depends from Claim 1 and recites the system of Claim 1 further comprising a chamber that can accommodate a variable increase in the therapy fluid during treatment. The system is described in paragraphs [0081] and [0088] as including these elements, along with a fresh supply of dialysate (not shown). Paragraph [0081] describes the system as including a catheter 48 and a fluid loop 42, the fluid loop including pumps 44. Fluid loop 42 includes a chamber 49 for accumulating an increase in therapy fluid volume and states that a fresh supply of dialysate (not shown) may be included. Paragraph [0088] notes that the system includes a cleaning cartridge 50 coupled to the loop 42, the cleaning cartridge including several layers 54, 56, 58, as well as a back pressure regulator 59.

Claims 1 and 10 as filed, in combination with the description in paragraphs [0081] and [0088], and Fig. 3A, describe the invention recited in amended Claim 1. The application as filed thus offers support for the claim term "consisting of." Information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application, such as the claims, without introducing new matter. M.P.E.P. 2163.06. No other components or elements are required for the system, and thus Applicants respectfully submit that the added words "consisting of" do not constitute new matter. The same arguments hold for Claims 13 and 24 as presently amended.

The description is sufficient to demonstrate that applicants were in possession of the claimed invention, that applicants have invented the subject matter of the claims, and that the patent describes the technology that is sought to be patented. M.P.E.P. 2163 I. Applicants accordingly respectfully request that the Examiner withdraw the rejection under § 112, first paragraph.

3. Claims 7 and 29 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action states that the phrase "ion exchange resin" constitutes new matter. Applicants point to the specification as originally filed, paragraph [0087]. This paragraph states that the cleaning cartridge may have the capability to remove all or a portion of electrolytes, such as sodium, potassium, or the like, from the dialysate solution, and that the cartridge may also be configured to release bicarbonate or the like into the system depending on the type of sorbent, and that pH may also be regulated by such releases.

It is well known to those with skill in dialysis or chemical arts that sodium, potassium and bicarbonate are present in dialysis solution as ions,  $\text{Na}^+$ ,  $\text{K}^+$  or  $\text{HCO}_3^-$ . It is also well known that pH is most easily regulated with  $\text{H}^+$  or  $\text{OH}^-$  ions, as well as with ions such as bicarbonate,  $\text{HCO}_3^-$ . Accordingly, there is explicit support for the exchange of ions in Applicants' system. The passage in paragraph [0087] discusses absorption and release of ions into dialysis solution using sorbents in the cartridge. Applicants submit that the obvious meaning of the cited paragraph to those with ordinary skill in the art is the use of an ion exchange resin as a component of a sorbent in the cartridge. One definition of an ion exchange resin is an insoluble material of high molecular weight that contains groups which can be exchanged with ions in a

solution with which it is in contact. Merriam-Webster's Collegiate Dictionary, 10th ed. at 617. There is thus explicit support for the claimed ion exchange resin.

Applicants also contend that the description in the cited paragraph defines the functions of an ion exchange resin. Possession of the invention may be shown in a variety of ways, such as by describing characteristics sufficient to show that the applicant was in possession of the claimed invention. M.P.E.P. 2163 I, citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). The description is sufficient to demonstrate that applicants were in possession of the claimed invention, that applicants have invented the subject matter of the claims, and that the patent describes the technology that is sought to be patented. M.P.E.P. 2163 I.

To comply with the written description requirement, each claim limitation must be explicitly, implicitly or inherently supported in the originally filed disclosure, which support Applicants have now shown. M.P.E.P. 2163.05. Accordingly, the patent application possesses sufficient explanation to satisfy the requirement of the patent laws for a written description of the subject matter of Claims 7 and 29. The Examiner is accordingly respectfully requested to withdraw the written description rejection for Claims 7 and 29.

4. Claims 1, 2, and 5-12 are rejected under § 103(a) as unpatentable in view of U.S. Pat. No. 6,254,567 to Dennis Treu et al. ("Treu") in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). As to Claim 1, Treu discloses in Fig. 2 at least one pressure sensor (76, 78) coupled to the fluid circuit for sensing a pressure. Office Action, p. 6, lines 15-16. Treu does disclose that the pressure sensors are not necessary, but if they are not used, he requires an additional outlet pump. Treu, col. 10, lines 8-12. Treu also depicts additional circuit elements, such as valves 80, 92, which are not present in Claim 1, that preclude a finding of obviousness of Claim 1. See Figs. 1-2.

Accordingly, Treu does not teach or suggest a fluid circuit as claimed, i.e., consisting (only) of the claim elements recited in Claim 1. Claim 1 is therefore allowable, as are the claims depending from Claim 1, Claims 2 and 5-12.

Certain of the dependent claims are also not taught in Treu and Roberts. For example, Treu, col. 1, line 24, is cited for the ion exchange resin recited in Claim 7. Treu col. 1, line 24

states that kidney waste products include solutes with sodium and chloride ions and other compounds excreted through the kidneys. There is no teaching or suggestion here of an ion exchange resin, only that dialysis is intended to make up for the missing body functions of patients with kidney disease. Applicants respectfully submit Claim 7 is accordingly not obvious in view of the reference cited.

5. Claims 13, 14, 16-20, 22, 23 and 24-30 are also rejected under 35 U.S.C. § 103(a) as unpatentable in view of Treu in view of Roberts, as are Claims 3, 4, 15 and 21. These claims are also rejected in view of Treu, Fig. 2. By the same reasoning discussed above for Claim 1, Claims 13 and 24 are also not obvious in view of the references. Claims 14, 16-20, 22, 23 and 25-30 depend from Claims 13 and 24 and are allowable because Claims 13 and 24 is allowable. Claims 3, 4, 15 and 21 are allowable because they depend from allowable Claims 1 and 13. In addition, numerous of the dependent claims are also not obvious in view of the references. For example, Claim 29 recites the ion exchange resin discussed above in the rejection of Claim 7. These claims are allowable and the Examiner is respectfully requested to withdraw the rejections.

6. Applicants submit that the claims are in condition for allowance, and respectfully request issuance of a Notice of Allowance. If the Examiner believes that a telephone conversation would expedite prosecution in this case, or would be of use to the Examiner, she is respectfully requested to call the undersigned.

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Respectfully submitted,

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